REMARKS

Claims 8-15 are pending in the application.

Rejection under 35 U.S.C. 103

Claims 8-14 stand rejected under 35 U.S.C. 103 (a) as being unpatentable over *Colman et al. (US 5,665,065)* and *Fodor et al. (US 6,309,822).*

The examiner argues that *Coleman et al.* teach a medication infusion device comprising a compact programmable medication infusion pump or a pen or a syringe f0or dispensing prescribed medication such as insulin. A sensor or meter for detecting a current patient parameter such as a blood glucose reading is provided and the measured parameter is e.g. input to the pump controller for altering the medication delivery protocol in an appropriate manner. In accordance with *Colman et al.* the dispensing protocol can be automatically implemented or the patient can make changes by means of a visual display etc. The examiner refers to various text portions throughout the reference (col. 2, lines 46-64; col. 2 line 65, to col. 3, line 11; col. 5, lines 15-40; col. 5, lines 41-60).

As regards claim 8, examiner states that the medicine dispenser of *Colman et al.* is considered to be equivalent to claimed dosimeter containing a medication. The dosimeter such as the delivery pen is considered a chip and comprises dispensing means for the medicine. The sensor of *Colman et al.* is equivalent to the claimed diagnostic indicator system comprising a detector. The dosimeter and the diagnostic indicator system are interconnected and dosage information is supplied to the dosimeter for dispensing the medication in accordance with received information regarding the dosage.

The Examiner states that *Colman et al.* does not disclose that the sensor is for detection of genetic properties determined by gene expression testing but the examiner states that *Colman et al.* is not limited to glucose sensing and infusion of insulin as it is repeated throughout *Coleman et al.* that glucose reading is only an example and that the disclosed device/method can be used for other medications as stated in col. 2, lines 33-37 ("current patient condition parameter" and appropriate "medication delivery protocol for the patient"). The examiner refers to col. 3, lines 46-49; col. 3, lines 6-11; col. 3, lines 49-58; in support of her position. The Examiner therefore concludes that the glucose sensor is to be understood only as an exemplary type of sensor and that it is apparent that the teaching of *Colman et al.* is not limited to the use for blood glucose readings and delivery of insulin.

The Examiner therefore suggests that *Colman et al.* can be modified to detect other desirable diagnostic indicators of a medical condition and can be used to deliver appropriate medication for that medical condition. Examiner states that a general teaching to be derived from *Colman et al.* is a combination device comprising a diagnostic device and a medical delivery device that can be modified to diagnose known medical conditions and deliver appropriate medication. The skilled artisan would therefore look at other diagnostic sensors such as *Fodor et al.*

Examiner states that *Fodor et al.* discloses that expression levels of disease markers are compared to levels in healthy persons for diagnostic purposes and correlation of deviations with a pathological condition provides a diagnostic assay for a condition (col. 43, lines 24-52). Examiner further states that blood samples can be used for diagnosing an enormous number of parameters and that a fingerprinting method as that of *Fodor et al.* provides similarly the ability to diagnose particular medical conditions and to apply preventive medicine (col. 89, lines 49-63). *Fodor et al.* discloses microarrays for diagnostic assays (col. 94, lines 53-61; col. 95, lines 62-67; col. 96, lines 28-41; col. 98, lines 28-35; col. 98, lines 36-42; col. 98, lines 43-51). Kits with compartments with the necessary reagents are disclosed (col. 90, lines 4-9). In examiner's opinion, it would therefore have been obvious to skilled artisans to combine *Colman et al.* and *Fodor et al.* because *Colman et al.* discloses combination of medication dispenser and diagnostic sensor providing data for the dispensing protocol and is not limited to glucose/insulin so that the skilled artisan would have recognized benefits of utilizing such teachings for diagnosis of other medical conditions (based e.g. on the disease markers disclosed in *Fodor et al.*) and treat these medical conditions as taught by *Colman et al.*

Applicant respectfully disagrees with examiner's position, in particular that a person skilled in the art would look at *Fodor et al.* as an alternative to the glucose/insulin scheme.

Coleman et al. teach simply continuous measuring/monitoring of a blood glucose level by means of a glucose sensor and a device for injecting insulin in accordance with the measured glucose level, i.e., the medication is applied in response to a measured value that is directly influenced by the medication to be administered. This has nothing in common with the claimed combination package with an indicator system based on gene expression testing in order to determine a patient's individual fingerprint for selecting a

proper medication and/or dosage before starting a therapy. This has been discussed in detail in the last amendment dated 11/11/2008.

Colman et al. also does not mention anything in regard to gene expression testing. If anything, the reference suggests the use of blood chemistry readings in general (col. 1, lines 61-65), i.e., other readings of blood parameters than the glucose level could be the basis of administering a medication (e.g. thyroid hormone > thyroid medication; cholesterol/triglycerides > cholesterol-lowering drugs etc.). But there is certainly no suggestion or motivation to look at gene expression testing based on *Coleman et al.*

Fodor et al. discloses a method for comparison and identification of differences in nucleic acid sequences by employing a plurality of sequence specific reagents. Possible applications of the method described in this reference are disclosed in col. 97/98. For example, the method can be utilized in large scale hybridization assays and genome mapping. DNA sequencing and genetic diagnosis (col. 97, lines 21ff). In col. 97, lines 40ff, it is disclosed that the method can be used in genetic diagnostics in that mutant nucleic acids are reacted with patient DNA. The response to certain drugs or environmental factors is supposedly determinable also (col. 97, lines 66ff).

The disclosed methods and arrays of *Fodor et al.* relate exclusively to possible diagnostics and there is no correlation being made to administering medication in response to the test results. As stated in the Abstract, the "*invention provides methods for comparing and identifying differences in nucleic acid sequences using a plurality of sequence specific recognition reagents (i.e., probes comprising a nucleic acid complementary to a nucleic acid sequence in collections to be compared) bound to a solid surface.*". *Fodor et al.* provides no suggestion as to using the assays disclosed therein for the purpose of administering or metering a medication in response to the test results. In particular, a individual patient-dependent dispensing of the active ingredient is not disclosed.

As regards examiner's remarks concerning a blood sample providing a number of different physiological conditions and the fingerprint embodiment of *Fodor et al.* becoming a routine means, like blood work, for diagnosing an enormous amount of physiological features simultaneously, it is not seen how this could be a suggestion to use the assay of *Fodor et al.* ("*providing an enormous amount of physiological features*") in the combined sensing and metering device according to *Colman et al.* The enormous amount of

physiological features would require an enormous amount of various medications in order to be able to respond to the measured results, should any of the physiological features as measured require treatment. This is simply unfeasible.

Also, in regard to examiner's reference to col. 89, lines 49-53, as regards "preventive medicine", it is respectfully submitted that this does not mean that a medication is administered preventively. Preventive medicine is a medical specialty that is concerned with "*measures taken to prevent illness or injury, rather than curing them. This type of care is best exemplified by hand washing and immunizations. It can be contrasted not only with curative medicine, but also with public health methods (which work at the level of population health rather than individual health).*". Please see attached copy of Wikipedia on the subject of "Preventive Medicine". This article also sets forth that "*Preventive care may include examinations and screening tests tailored to an individual's age, health, and family history. For example, a person with a family history of certain cancers or other diseases would being screening at an earlier age and/or more frequently than those with no family history.*". Thus, preventive medicine does not mean that a medicament is being applied but only that medical procedures (for example, immunization, surgery etc.) are initiated. There is no disclosure in regard to applying a medication in response to the genetic testing done by the assays of *Fodor et al.*

Fodor et al. therefore is directed strictly to diagnostics and there is no correlation to administering a medication based on the results of the (broad) assays. *Fodor et al.* do not provide any examples where the assay indicates a medical condition and where it is proposed to use a medication to treat the condition based on the assay. The entire reference only refers to diagnostics/screenings. See the section "B. Utility" (col. 97, line 21, to col. 98, line 51; emphasis added):

"*Microarrays of immobilized nucleic acid sequences prepared in accordance with the invention can be used for large scale hybridization assays in numerous genetic applications, ..., monitoring of gene expression, ...,* ***genetic diagnosis****, ...*

For gene mapping, ...

The arrays of immobilized DNA fragments may also be used for ***genetic diagnostics****. To illustrate, an array containing multiple forms of a mutated gene or genes can be probed with a labeled mixture of a patient's DNA which will preferentially interact*

with only one of the immobilized versions of the gene.

The detection of this interaction can lead to a medical diagnosis. Arrays of immobilized DNA fragments can also be used in ***DNA probe diagnostics****. ...*

In one application, an array of cDNA clones representing genes is hybridized with total cDNA from an organism to monitor gene expression for research or ***diagnostic purposes****. ...*

By way of example and without implying a limitation of scope, such a procedure could be used to simultaneously ***screen many patients against all known mutations in a disease gene****....*

The assay format can be reversed ... ELISA assays. Furthermore, the invention allows for the use of all ***standard detection methods*** *without the need to remove the shallow barrier elements to carry out the detection step.*

In addition to the genetic applications listed above, arrays of whole cells, peptides, enzymes, antibodies, antigens, receptors, ligands, phospholipids, polymers, drug cogener preparations or chemical substances can be fabricated by the means described in this invention for large scale screening assays in ***medical diagnostics****, drug discovery, molecular biology, immunology and toxicology.*

The multi-cell substrate aspect of the invention allows for the ***rapid and convenient screening*** *of many DNA probes against many ordered arrays of DNA fragments. This eliminates the need to handle and detect many individual arrays for perfoming* ***mass screenings*** *for genetic research and diagnostic applications. Numerous microarrays can be fabricated on the same solid support and each microarray reacted with a different DNA probe while the solid support is processed as a single sheet of material.".*

The *Fodor et al.* reference provides no motivation or suggestion to employ the diagnostic assays disclosed therein as a detection tool in the sensor/dispenser device of *Colman et al.* as *Fodor et al.* only teaches assays but do not teach any combination of a condition to be assayed and a medication to be metered and administered in response to the assay readings. Therefore, a person skilled in the art will not derive any teaching from *Fodor et al.* in regard to how the device of *Colman et al.* could be modified for other detection/administration uses. The teaching of a diagnostic assay alone cannot provide a

suggestion to use such an assay in a combination device for determining a patient-specific medical condition and metering or dispensing a medication in response.

Moreover, there is no suggestion or motivation to apply a method that concerns comparison and identification of differences in nucleic acid sequences to a method for metering glucose/insulin. The fact that *Fodor et al.* discloses a method for gene expression testing does not provide motivation to a person skilled in the art to modify the glucose/insulin treatment device to a device for treating a medical condition detected by gene expression testing absent any lead in regard to how the treatment could be achieved. *Fodor et al.* only concerns testing and not treating. There is simply no teaching in either *Coleman et al.* or in *Fodor et al.* to consider gene expression testing for a sensor/metering combination as disclosed in *Colman et al.* where at most there is a suggestion in *Colman et al.* to employ a different blood reading as a basis for modifying the device.

Also, the glucose measurements proposed by *Colman et al.* only mean that values are determined as regards the level of glucose in the blood but not how a patient reacts or does not react to certain medications based on his/her constitution. *Colman et al.* does not relate to specific responder/non-responder effects as discussed and claimed in the present invention (claim 15) and specific reactions of patients are not taken into account (aside from manual input through display means).

In contrast to the cited references, the present invention is directed to the individual and very specific genetic property of a patient that is to be determined. This is in particular based on responder/non-responder property (claim 15). An important feature of the present invention is that the individual reaction or genetic predisposition of patients can be taken into consideration for the treatment and dispensing of a medication. This is neither disclosed in *Colman et al.* nor in *Fodor et al.* and is not obvious when combining both teachings.

The claims 8-15 are therefore not obvious in view of *Colman et al.* and *Fodor et al.*

Reconsideration and withdrawal of the rejection of the claims 8 to 14 under 35 USC 103 are respectfully requested.

CONCLUSION

In view of the foregoing, it is submitted that this application is now in condition for allowance and such allowance is respectfully solicited.

Should the Examiner have any further objections or suggestions, the undersigned would appreciate a phone call or **e-mail** from the examiner to discuss appropriate amendments to place the application into condition for allowance.

Authorization is herewith given to charge any fees or any shortages in any fees required during prosecution of this application and not paid by other means to Patent and Trademark Office deposit account 50-1199.

Respectfully submitted on March 16, 2009,

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GEH
Encl.: Wikipedia "Preventive Medicine"

Preventive medicine

From Wikipedia, the free encyclopedia

Preventive medicine or **preventive care** is measures taken to prevent illness or injury, rather than curing them. This type of care is best exemplified by hand washing and immunizations. It can be contrasted not only with curative medicine, but also with public health methods (which work at the level of population health rather than individual health).

Professionals involved in the public health aspect of this practice may be involved in entomology, pest control, and public health inspections. Public health inspections can include recreational waters, pools, beaches, food preparation and serving, and industrial hygiene inspections and surveys.

Preventive care may include examinations and screening tests tailored to an individual's age, health, and family history. For example, a person with a family history of certain cancers or other diseases would being screening at an earlier age and/or more frequently than those with no family history.

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As a medical specialty

In the United States, preventive medicine is a medical specialty, one of the 24 recognized by the American Board of Medical Specialties (ABMS). It encompasses three areas of specialization:

- General preventive medicine and public health
- Aerospace medicine
- Occupational medicine

In order to become board-certified in one of the preventive medicine areas of specialization, a licensed U.S. physician (M.D. or D.O.) must successfully complete a preventive medicine medical residency program following a one year internship. Following that, the physician must complete a year of practice in that special area and pass the preventive medicine board examination. The residency program is at least two years in length, and includes completion of a post-graduate masters degree in public health (MPH) or equivalent. The board exam takes an entire day: the morning session concentrates on general preventive medicine questions, while the afternoon session concentrates on the one of the three areas of specialization that the applicant has studied.

In addition, there are two subspecialty areas of certification:

- Medical toxicology (MT)
- Undersea and hyperbaric medicine (UHB), formerly "undersea medicine"

These certifications require sitting for an examination following successful completion of an MT or UHB fellowship and prior board certification in one of the 24 ABMS-recognized specialties.

Rose's theorem

Rose's Theorem states that "a large number of people at small risk may give rise to more cases of disease than a small number who are at high risk."[1]

Leading cause of preventable death

See also: Preventable causes of death

Leading causes of preventable deaths in the United States in the year 2000.[2]

Cause	Number of deaths resulting
Smoking	435,000 deaths or 18.1% of the total deaths
Overweight and Obesity	365,000 deaths or 15.2% of the total deaths.
Alcohol consumption	85,000 deaths or 3.5% of the total deaths.
Infections	75,000 deaths or 3.1% of the total deaths.
Toxic agents	55,000 deaths or 2.3% of the total deaths.
Motor vehicle collisions	43,000 deaths or 1.8% of the total deaths.
Incidents involving firearms	29,000 deaths or 1.2% of the total.
Sexually transmitted infections	20,000 deaths or 0.8% of the total.
Illicit use of drugs	17,000 deaths or 0.7% of the total deaths.

See also

- Functional food

References

1. ^ Rose, G.: *The Strategy of Preventive Medicine.* Oxford, England, Oxford University Press; 1992.
2. ^ Mokdad AH, Marks JS, Stroup DF, Gerberding JL (March 2004). "Actual causes of death in the United States, 2000 (http://www.csdp.org/research/1238.pdf)". *JAMA* **291** (10): 1238–45. doi:10.1001/jama.291.10.1238 (http://dx.doi.org/10.1001/jama.291.10.1238). PMID 15010446 (http://www.ncbi.nlm.nih.gov/pubmed/15010446). http://www.csdp.org/research/1238.pdf.

External links

- Association of Preventive Medicine Residents (http://acpm.org/apmr.htm)

- US Preventive Medicine (http://www.uspreventivemedicine.com/)
- The Prevention Plan (http://www.thepreventionplan.com/)
- American College of Preventive Medicine (http://www.acpm.org/)
- American Board of Medical Specialties (http://www.abms.org/)
- American Board of Preventive Medicine (http://www.abprevmed.org/)
- American College of Veterinary Preventive Medicine (http://www.acvpm.org/cgi-bin/start/index.htm)

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